

Study Title: **The acceptability and feasibility of an ED-based, peer-delivered, suicide safety planning intervention**

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Background and Rationale

Scientific rationale: Suicide deaths are increasing

Suicide is a leading— and growing— cause of death in the United States.¹ From 2008-2017, suicide was ranked the 10th leading cause of death for all ages combined, and from 1999-2017, the age-adjusted suicide rate rose by 33%.² Thus, suicide is a large problem nationwide.³

Safety planning is a brief, ED-feasible intervention which has been demonstrated to save lives,^{4,5} and has been universally recommended by every recent expert consensus panel on suicide prevention strategies.^{3,6-8} In one popular version of the safety plan developed by Stanley et al,⁴ the patient is encouraged to write out the following items: identifying personal signs of a crisis; helpful internal coping strategies; social contacts or settings which may distract from a crisis; using family members or friends for help when in crisis; mental health professionals who can be contacted when in crisis; and restricting access to lethal means.⁴ In most emergency departments, safety-planning is done by clinical personnel such as psychologists or social workers, but these providers are often too busy to perform safety-planning well or have multiple other patient care responsibilities.

This project aims to answer the following three research questions: (1) In general, do ED patients with suicidal ideation/attempt prefer to interact with/receive support from peers with life experiences of suicide or clinical professionals who might have such life experiences or not? (2) Will patients with suicidal ideation/attempt accept a peer-delivered safety planning intervention as opposed to one delivered by clinical personnel? (3) Are peer-delivered safety plans of equal quality as those delivered by clinical personnel?

Please note that the study will not otherwise alter usual or customary care in the emergency department.

Rationale for testing peer-delivered interventions in the ED

The rationale for testing a peer-delivered intervention in the ED relies on the following evidence: a) a peer is an individual with lived experience who is now supporting other mental health patients in crisis; b) the experience of a mental health patient in the ED often shapes the perception of the health system, and may influence willingness to seek future care;⁹ c) peers may provide more empathetic care than providers without lived experience, which may positively impact patients; d) peer-based programs for patients with serious mental illness that do not involve safety planning are at least as good as non-peer based programs at preventing hospitalizations and promoting engagement in care, with the most promising interventions involving self-management or peer-navigator roles;¹⁰ and e) existing evidence from high-quality studies is scarce, but in moderate-low quality studies has indicated that peers are no less effective than mental health workers.¹¹ However, even if peers are also no more effective than mental health workers in the same role, it is likely more economically feasible to employ peers compared to more costly mental health staff. Please note that as economic costs of a peer-delivered safety plan have never been studied formally, the investigators will conduct a time analysis of peers in the ED in order to calculate potential costs.

As noted in a previous systematic review by Lloyd-Evans et al¹² and a 2013 Cochrane review by Pitt et al,¹¹ there is little high-quality evidence regarding the benefits of peers in mental health settings. Where high-quality evidence exists, available studies have generally demonstrated that, outside of a reduction in emergency department usage, peer support is not worse than trained mental health workers in the same role.¹¹ However, this conclusion primarily relies on evidence from outpatient studies,^{11,13} not the ED. In addition, existing studies have included peers in a variety of roles interacting with patients who had a variety of mental health conditions.

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Concerns about peer vulnerability to relapse

Anecdotally, there have been concerns that peer-delivered interventions may not be effective in the ED, since peers may be vulnerable to relapse in the stress of the acute-care environment. As some authors have noted, working in acute care is stressful for many individuals, not just peers.¹⁴ However, it is not true that peers are too “fragile” for a study of this type. Findings from peers in non-ED environments have generally indicated that peers receive positive benefit from the experience,¹⁵ including increased confidence and self-esteem.¹⁶ Nonetheless, peers will be given the opportunity to experience the ED environment before committing to this project (please see “Recruitment of peers for this project” and “Training of peers” below). In addition, peers will be closely monitored and debriefed by the sub-investigator of this project (Waliski), who is a licensed clinical counselor (please also see “Supervision and debriefing of peers” below). While adverse events are not expected as a result of this intervention, the PI will carefully monitor for any such event and report any adverse event to the IRB. In addition, if a peer has a relapse or any psychiatric emergency during the course of the intervention, they may contact Dr. Waliski using the contact information provided during peer training. After this initial contact, Dr. Waliski will debrief the peer by meeting with them and further discussing the situation.

Please note that although peers will receive mandatory confidentiality training required at the study institution, there is little concern that peers will “say the wrong thing” or break a patient’s confidentiality. Given that these peers have personal experience of hospitalization, it is more likely that they will be willing to guard the patient’s confidentiality and less likely than clinical staff to make insensitive remarks to a patient. However, all peers will be CITI-certified, with periodic reminders about patient confidentiality from the investigators.

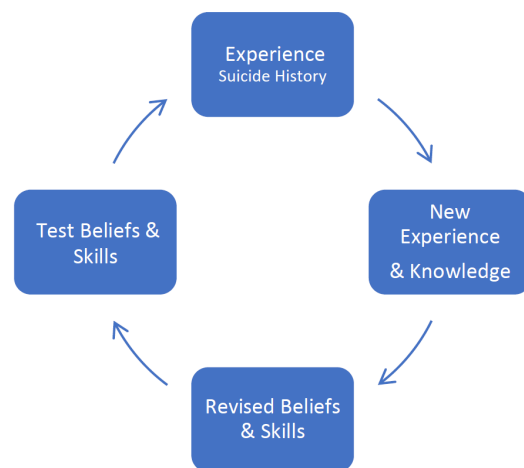
Recruitment of peers for this project

Peers will be recruited through existing relationships with community suicide prevention organizations (i.e. Arkansas Foundation for Suicide Prevention, Arkansas Governor’s Suicide Prevention Council, Veterans Service Organizations, etc.). Eligible recruits will complete an interview with Dr. Waliski where they will be informed about the responsibilities and expectations becoming a peer. Recruits will be asked to briefly give an overview of their suicide history and treatment history. Training and supervision of peers (please see “Training of peers” and “Supervision and debriefing of peers” below) will be used to further monitor the appropriateness of the individual to assist patients in providing the intervention.

Training of peers

As this project utilizes individuals that have lived through serious suicidal ideation or attempts, training, debriefing, and supervision of research staff are paramount (please see “Supervision and debriefing of peers” below). Training will follow constructivism learning theory,¹⁷ which posits that individuals learn best when they actively construct their own meaning of new information by relating it

Figure 1: Suicide safety planning training cycle



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to their experiences, attitudes, and beliefs.^{18,19} In this mode of instruction, instructors facilitate learning by asking guiding questions and providing individualized feedback, utilizing role play and role modeling, and providing a safe learning environment that promotes self-exploration and self-evaluation.¹⁸⁻²⁰

As shown in the Suicide Safety Planning Training Cycle (please see figure), training conducted by sub-investigator Waliski, sub-investigator Thompson, and PI Wilson will extend over approximately 12 hours (please see “Training agenda” uploaded to the IRB as a separate document). Training will involve a four-step cycle that starts with exploring personal experiences about suicide and suicide prevention. Using videos, presentation slides, and active learning techniques, students will be provided education about suicide and the safety planning intervention using training materials originally developed by Drs. Stanley and Brown.²¹ The information presented to the student may be new or previously known by the student, but will be presented in a way that encourages deeper examination of the topic and how it relates to the student’s experiences. The instructor will then facilitate the revision of beliefs and skills using guiding questions and individualized feedback based on student comments. Examination and exploration will promote the revision of the student’s knowledge and beliefs about suicide and the safety planning intervention. Finally, role modeling and role play will be used to allow the student the opportunity to test their now-revised beliefs and skills related to suicide and safety planning intervention. This is an iterative process and will be performed as many times as needed for each student.

Specific training will be conducted about how to conduct the safety plan intervention, using materials developed by Brown & Stanley. Five learning objectives will guide the development of the training structure (please see Table I). The instructor (Drs. Thompson & Waliski) will present information using various didactic and technological methods, and will take place over approximately 12 hours. During initial topics, the focus will be on building a safe learning environment that utilizes the student’s personal life experiences to understand empirical evidence of suicide and suicide prevention. Later

Table I: Learning objectives in suicide safety planning training

Learning Objective	Learning Activities
1. Demonstrate active listening, genuineness, respect, and a desire to assist individuals at risk of suicide	<ul style="list-style-type: none">• Videos and Powerpoints about suicide and suicide prevention• Role play with instructor and other students
2. Demonstrate ability to develop a safety plan	<ul style="list-style-type: none">• Develop a personal suicide safety plan• Complete a safety plan using a written case study• Complete a safety plan as part of a role play activity• Verbalize plan to maintain appropriate self-care
3. Appropriately disclose personal experiences as a survivor suicidal ideations or attempts	<ul style="list-style-type: none">• Discuss beliefs of suicide and suicide prevention• Instructor will role model appropriate reflections of personal suicide experience• Practice appropriate self-disclosure
4. Demonstrate the ability to problem solve, risk assess, make suggestions for multi-professional referrals to maintain and ensure patient safety	<ul style="list-style-type: none">• Review referral and resource guide• Use case studies to practice how to appropriate refer for services and care
5. Demonstrate effective data collections and management	<ul style="list-style-type: none">• Review policies and procedures for data collections and management• Use case studies to practice data collection and management

topics will provide more specific training on the safety plan using materials from Brown and Stanley.²¹ This portion of the training will also use videos, presentations, and role-playing. While lists of examples of warning signs, strategies for internal and external distractions, methods for restricting lethal means, and mental health treatment providers will be provided, students will be encouraged to provide input

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based on their own experiences. Finally, training will also involve a general orientation to the emergency department. This part of the orientation will be provided by Dr. Wilson, and will involve already-developed training materials for orienting new research staff to the UAMS ED. Follow-up trainings will be provided depending on identified needed.

Special training about COVID-19: patients presenting to the UAMS ED are universally screened for COVID-19 signs or symptoms (fever, cough, recent travel) and are placed into specially-marked isolation rooms. As part of training, peers must demonstrate awareness of ED policies regarding the marking of these isolation rooms for suspected COVID-19 patients; must understand the importance of not entering these rooms; must understand and agree to use hand sanitizer when entering and leaving a patient's room ("foam in/foam out"); must demonstrate awareness of UAMS policies regarding screening of employees when they arrive for work; and must agree to stay home if they are feeling sick.

Please note that safety planning is a process that requires in-person interaction with participants due to the setting involved and confidentiality concerns. Having the special training detailed above in place reduces the health risk to potential participants and research staff. In addition to using the special training about COVID-19 detailed above, research staff will further minimize health risk by maintaining a safe social distance from participants during all study procedures and properly sanitizing all study equipment (pens, tablets, etc.) by using sanitizing wipes after use by each participant.

Supervision and debriefing of peers

Although anecdotally peers may be vulnerable to stress-induced relapse in the ED clinical environment, scant support for this idea is noted in the literature (please see above). Nonetheless, all peers will receive close supervision and debriefing during the study. Supervision will be provided using the discrimination model.²²

As a licensed clinical counselor, Dr. Waliski will assess the provider's skill level and will become the role of a teacher, counselor, or consultant based on need. In other words, peers and mental health staffs will be provided with either instruction and direct feedback (i.e., the teacher role), support for reflection and processing of personal experiences (i.e., the counselor role), or encouraging confidence in required skills (i.e., the counselor role) depending on need.

In terms of direct supervision, Dr. Waliski will be on site during the first week of the intervention to observe performance and operation. She will ensure that the safety plan is being administered, documented, and managed appropriately by each provider (see also "Fidelity of the intervention" below). If deficits are identified, she will work with individuals to make needed improvements. During the first week of intervention implementation, Dr. Waliski will also conduct an individual face-to-face interview with each peer. Interview questions will be guided by the Consolidated Framework for Implementation Research (CFIR)²³ and focus on identifying and overcoming perceived barriers to implementation of the intervention.

Peers will also be provided with clear instructions on how to obtain help during any difficult or uncomfortable situations during the intervention. After the first week of the intervention, peers may inform ED clinical staff (social worker or psychiatric nurse) on site of such situations so that the staff may continue working on the safety plan with the participant. ED clinical staff are available 24/7 so peers would not have much trouble in finding and asking someone for help with a participant during these situations. Participants who do not complete the safety planning with a peer will be withdrawn from the study, but peers will be informed that their safety and well-being remains a priority when completing the intervention and so they should not hesitate to ask clinical staff for help. Peers may also contact Dr.

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Waliski using the contact information provided during peer training in order to schedule an in-person meeting. Dr. Waliski will debrief the peer at these meetings by further discussing the difficult or uncomfortable situations.

Once the pilot project is underway, periodic debriefing of peers will be provided by Dr. Waliski. This debriefing will provide an opportunity to identify areas of needed improvement in the study protocol or in training (please also see “Fidelity of the intervention” below). Given this study utilizes individuals that have lived through serious suicide ideations and/or attempts, peers will likely have their own preconceived opinions about suicide and how to encourage survival. Debriefing will allow an opportunity to monitor how past experiences could be impacting the delivery of the intervention or how participating in the study could be impacting the peer. Dr. Waliski will also use this time to review personal safety plans and encourage peers to participate in appropriate self-care.

Description of interventions

Written safety plan: Please see separate upload for the Stanley et al version of the safety plan. The safety plan contains 6 components, and is completed by the patient. This intervention takes approximately 20-40 minutes to complete. As a former site for the ED-SAFE study,²⁴ the UAMS ED typically has patients complete safety plans if being discharged and if trained staff is available. Trained staff are typically available weekdays, and usually consist of a psychiatric nurse or social worker. These clinical providers typically place a progress note containing the patient’s safety plan in the electronic medical record (EMR), and must approve all safety plans in this study, as peer supporters/research staff do not have the ability to place notes in the EMR.

Study Design and Procedures

This is an effectiveness-implementation randomized controlled trial which will be conducted at the emergency department (ED) at the University of Arkansas for Medical Sciences (UAMS) in Little Rock, Arkansas. The UAMS ED is an urban emergency department which sees approximately 60,000 patients per year, including more than 1,200 suicidal patients.

This clinical trial will compare the intervention of ED patients completing a written safety plan with a peer to completing a written safety plan with clinical personnel. Patients triaged and flagged with the chief complaint of “SI” or “suicidal ideation” on the ED trackboard when a peer is available will be approached to participate. Patients will be approached after evaluation by an emergency physician.

Please note that clinical staff will be notified when a peer is on site by posting of a flyer that is visible only to clinical staff, not patients. This flyer is not meant for the purpose of recruiting patients, but will be utilized solely to inform clinical staff of the ongoing study.

Study flow: Utilizing a peer with lived experience of suicide (e.g., history of suicidal ideation/attempt prior to last year; loss of immediate family member to suicide), ED staff will approach patients identified from the ED trackboard as being at risk for suicide until as many as 32 patients have completed the study. Patients are typically triaged by UAMS nursing staff as being “at-risk” after questions about self-harm. If so triaged, patients are then flagged with the chief complaint “SI,” “suicidal ideation,” “suicide attempt,” or “Psychiatric BEE” on the ED trackboard. A partial waiver of HIPAA for recruitment purposes is requested to allow research staff to visualize the ED trackboard, and is appropriate for the following reasons:

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- The PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on the fact that no PHI will be recorded, reused, or disclosed to any other person or entity except as required by law or for authorized oversight of the research study.
- The research could not practicably be conducted without the requested waiver or alteration, as it would be difficult or impossible to identify ED patients at risk of self-harm in any other manner.
- The research could not practicably be conducted without access to and use of the PHI.

Please note that that the safety plan intervention will be delivered by individuals with lived experiences of suicide. These peers will receive training in both ED operations (by Dr. Wilson) and safety planning (Dr. Waliski), data collection techniques, how to operate REDCap data collection software, and how to obtain informed consent. All research staff will be CITI certified and will receive periodic reminders about confidentiality.

Upon approach by research staff, patients will be asked if they would like to participate in the study and if they would allow peers to help them with safety planning. If the answer to both questions is yes, patients will be offered a brief screening procedure:

Inclusion criteria: patients presenting for suicidal ideation (SI) or after suicide attempt to the UAMS ED; willingness to engage in safety planning with trained peers (non-clinical staff); have not already filled out a safety plan at the current visit.

Exclusion criteria: <18 or >89 years of age; incarcerated or in police custody; non-English speaking; critically-ill; unwilling or unable to complete the safety plan; unwilling or unable to show safety plan to clinical staff. Please note that patients may be unable to complete the safety plan for any of a number of reasons, including being actively psychotic, acutely manic, or intoxicated with alcohol/drugs. Patients will be evaluated for these inclusion/exclusion criteria by research staff.

If participants indicate interest in the study and meet all inclusion/exclusion criteria, informed consent will be obtained using IRB-approved consent forms & processes. If they provide consent, participants will then be asked to answer a short questionnaire concerning their demographics (e.g., age, gender) and any history of previous suicide ideation, attempts, or related behaviors.

After completing this short demographic questionnaire, participants (n=37) will be randomized in a 1:1 fashion to either the peer safety planning group, in which they will complete the safety plan with a peer, or the clinical personnel safety planning group, in which they will complete the safety plan with clinical personnel as usual (please see Figure 2). Participants will be randomized using the REDCap functionality for this purpose. All participants will be allowed to complete the written safety plans in the privacy of their ED treatment room. Please note that participants will be given a \$25 gift card for participating regardless of which group they are randomized into for the study.

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When a peer-delivered safety plan is completed, the UAMS ED psychiatric registered nurse or social worker will review and, if approved, enter the safety plan into the EMR. (Please see “Description of intervention” above.) Please note that the study will not otherwise modify care in the ED. It is possible, although not likely, that psychiatry consultants could choose to revise, edit, or otherwise start anew with safety planning for a particular patient. If such occurs, the participant will be removed from the study.

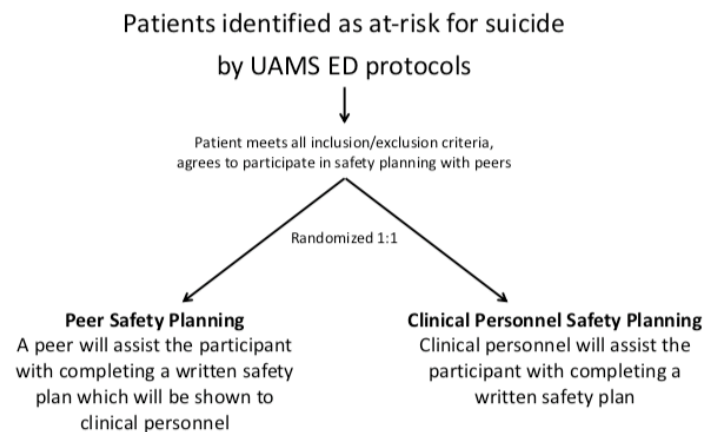


Figure 2. Study flow.

Other measures: All participants will complete a brief survey regarding their demographics and satisfaction with the safety planning process. After the visit, the electronic medical record will be searched for the following data: date/time of ED triage and disposition; length of ED stay; ED chief complaint or reason for visit; patient disposition (observation/admission/discharge/transfer); psychiatric diagnoses; and frequency of ED visits 3 months before and after the intervention. Length of ED stay will be compared against two control groups (obtained using AR-CDR): a) length of stay of all ED patients during a similar time period; and b) length of stay of ED patients who presented for SI during a similar time period. No PHI will be recorded for either of these deidentified control groups. Peers and clinical staff will also be asked to record the total amount of time that they spent performing the safety plan intervention.

Study retention: The study duration is limited to the ED visit (typically <6 hours for SI patients), with participation in the study limited to the safety planning intervention above. Consequently, no special measures designed to increase retention are planned.

Grading of safety plan quality

Safety plans created by peers will be approved by existing ED clinical staff after being created (see “Study design and procedures” above). Safety plans will also later be graded on a numerical rating scale (0-2 or 0-3, depending on grading component) by the investigators using materials developed by Gamarra et al for this purpose.²⁵ Using a “safety checklist,” responses for each of the 6 safety plan steps (with step 3 divided into two parts) and the “most important thing worth living for” section will be rated according to the personalization of the information in each section. In addition, each section will be independently rated for “completeness” (0=not complete, 1=partially complete, 2=complete) and “quality” (0=blank, 1=boilerplate, 2=some evidence of personalization, 3=highly personalized and specific). For example, warning signs (step 1) may be rated as “1” if the plan refers to non-specific thoughts such as “thinking about the future.” Responses may be classified as “3” if they contain fairly specific descriptions, such as “feel useless.” Each of the sections in a participant’s safety plan will be graded in this manner, with completeness having a maximum score of 16 and quality having a maximum score of 24. An overall score for the safety plan will be derived by adding the scores for all sections in a participant’s safety plan. Peers will be trained to coach participants towards higher-quality answers (please see “Training of peers” above).

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Monitoring: Adverse events or in case of psychiatric emergency

By definition, all patients have presented to the ED for an acute mental health crisis and will be under the care of trained ED physicians, trained ED nurses, trained psychiatric ED nurses who typically complete the safety plan, and other psychiatric personnel as appropriate. In the unlikely event of psychiatric decompensation, peers will be instructed to stop the intervention and seek help from qualified personnel in the ED. The intervention will then not be continued.

Although adverse events (AEs) are not expected and are unlikely, the peers and mental health personnel who are responsible for approving the safety plan will nonetheless be instructed to communicate any and all AEs to the PI (Wilson). The PI will communicate any adverse events to the UAMS IRB, consistent with IRB policies & regulations.

Risks and Benefits

The main potential risk to study participants is loss of confidentiality. The researchers take confidentiality very seriously, and measures to protect the confidentiality of study participants will be implemented as described in the Data Handling and Recordkeeping section below. Adverse events will be handled as above (please see “Monitoring: Adverse events or in case of psychiatric emergency” above).

Data Handling and Recordkeeping

The Principal Investigators will carefully monitor study procedures to protect the safety of research participants, the quality of the data, and the integrity of the study. All study participant material will be assigned a unique identifying code or number in REDCap. Only Dr. Wilson and select study staff will have access to the code and information that identifies the participant in this study. However, audits of deidentified data may be performed by the study sponsor at their discretion. Safety plan material of patients will also be kept in a locked file in the office of the PI or co-investigator. Access will be strictly limited to study staff. However, to guard against the very real possibility that these plans may allow identification of a particular patient despite having no identifying information, safety plans will not require the patient to record their name.

Records will be maintained for 7 years per IRB requirements. At the discretion of the PI, records may be scanned and maintained in electronic format instead of paper format once the study is complete. If so, electronic records will be audited to ensure high fidelity with the originals. REDCap data will be maintained on secure password-protected UAMS servers. When eventually destroyed, paper copies of safety plans will be shredded per UAMS disposal guidelines.

Data collection will be performed through both the CARS screener and the Research Electronic Data Capture (REDCap) system, and will be set up in cooperation with the UAMS Translational Research Institute (TRI) in order to assure 21 CFR Part 11 and HIPAA compliance.

Data Analysis

Outcome 1: Evaluate the proportion of SI patients approached in the ED who agree to receive a peer-delivered safety plan. This number is currently unknown.

Outcome 2: Evaluate the proportion of patients approached who meet all inclusion/exclusion criteria. This number may be lower than the number of patients willing to participate in safety planning.

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Outcome 3: Evaluate the quality of the completed safety plans. This will be done by retrospective review after the patient has left the ED. The number of safety plans that must be repeated or redone by the ED mental health clinician will also be tracked.

Outcome 4: Patient satisfaction with safety planning. This will be assessed by having the patient rate their experience with the safety planning process on a 7-point Likert scale (*strongly disagree; disagree; moderately disagree; neutral; moderately agree; agree; strongly agree*).

Power calculations and sample size: As this is a pilot study, no formal sample size calculation is planned. The investigators plan a priori to enroll up to 37 patients. The investigators therefore ask for permission to approach a maximum of 100 patients.

Initially, the randomization scheme will be validated by comparing the groups on key variables that could be associated with outcome (e.g., age, race, prior suicide attempts, prior completion of safety plan). Where we identify significant differences between groups, we will either adjust for these variables in analysis or conduct stratified analyses. Categorical variables will be analyzed with chi-square. Continuous variables will be analyzed by ANOVAs. Sub-analyses of potential prognosticators, including biological variables such as sex, will be descriptively presented, as the sample size will not likely permit sufficient testing of these variables.

Ethical Considerations

Written consent will be required for any study procedures. (Please see "consent form.") Please note that all study procedures will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board (IRB) to conduct the study.

Potential participants will be identified from the ED track board and/or patient triage note. This requires a partial waiver of HIPAA for recruitment purposes only. No PHI will be recorded or disclosed without patient consent. Please see study flow above.

Research staff will approach the patient in an ED treatment room only if this can be done privately and safely (please see "Training of peers" above). The consent process will also be done privately in the same room. No patients will be approached in the waiting room or in a hall bed. The formal consent of each participant, using the IRB-approved consent form, will be obtained before that participant performs any study procedure. All participants for this study will be provided a consent form describing this study and providing sufficient information in language suitable for participants to make an informed decision about their participation in this study. The person obtaining consent will thoroughly explain each element of the document and outline the risks and benefits, alternate treatment(s), and requirements of the study. The consent process will take place as described above, and participants may take as much time as needed to make a decision about their participation.

Participation privacy will be maintained and questions regarding participation will be answered. No coercion or undue influence will be used in the consent process, including the fact that the PI will not be involved in the recruitment process if he is working in the ED at the time as an attending physician. This consent form must be signed by the participant and the individual obtaining the consent. A copy of the signed consent will be given to the participant, and the informed consent process will be documented in each participant's research record.

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Dissemination of Data

Results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant.

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